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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICALS USA, INC. Plaintiff, v. BIOGEN INTERNATIONAL GMBH, Defendant.	Case No. _____ PLAINTIFF'S COMPLAINT DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, Teva Pharmaceuticals USA, Inc. ("Teva" or "Plaintiff"), submits this Complaint against Defendant Biogen Swiss Manufacturing GmBH (collectively, "Biogen" or "Defendant"), in connection with Biogen's breach of the August 25, 2020 Authorized Generic Distribution and Supply Agreement (the

"Agreement") between the Parties for the supply and distribution of an authorized generic version of Tecfidera®.

SUMMARY OF THE ACTION

1. Teva and Biogen entered into the Agreement for the supply by Biogen and the distribution by Teva of a so-called "authorized" generic version of the branded product Tecfidera®, a drug approved for treatment of Multiple Sclerosis (MS), in which the active pharmaceutical ingredient is dimethyl fumarate (the "Product"). Under the Agreement, a copy of which is attached as Exhibit A, Teva was to purchase the Product from Biogen, for Teva to then sell throughout the United States.

2. An authorized generic is a brand-name drug made by a brand manufacturer but marketed under a generic label.

3. Authorized generics are typically sold at a reduced price compared to the brand name drug and can be marketed by the company who markets the brand name drug or a third party licensee.

4. The Agreement is "[redacted]." Agreement at § [redacted].

5. Following the execution of the Agreement, and after Teva had purchased Product from Biogen, Biogen suspended Teva's distribution rights under the same.

6. The Agreement [redacted]

7. [redacted]

8. By terminating the Agreement and insisting that the suspension remain in effect, Biogen seeks both (a) to avoid its obligation to replace Product that short-dates due to suspension and, at the same time, (b) to deny Teva's sell-off rights.

9. Biogen's attempt to keep in place its suspension of Teva's distribution rights, notwithstanding its termination of the Agreement, is inconsistent with the plain language of the Agreement, its structure, and the intent of the parties, and appears intended merely to minimize Biogen's own financial losses in the wake of unsuccessful patent litigation on Tecfidera® and market challenges in one of its critical product areas.

10. Biogen improperly terminated the Agreement by restricting Teva's rights to sell off the Product inventory in its possession upon termination, while at the same time insisting that the suspension remain in place, thereby depriving Teva of any benefits of the Agreement.

11. Biogen took payment from Teva for millions of dollars of Product that, as a result of Biogen's bad faith tactics, is now sitting in Teva's inventory and is essentially worthless.

12. Biogen has enriched itself by taking payment from Teva and sticking Teva with what is now worthless Product.

13. Biogen has refused to compensate Teva for the costs of the Product that it sold Teva and that Biogen now refuses to allow Teva to sell.

14. Biogen's "heads I win, tails you lose" tactic has left Teva with Product inventory that it paid for but Biogen insists cannot be sold.

15. Further, Teva alleges as follows:

JURISDICTION AND VENUE

16. This Court has jurisdiction in this case over all causes of action asserted herein pursuant to 28 U.S.C. § 1332(a)(2) because plaintiff and defendant are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

17. Biogen conducts business within the United States of America and its territories, districts, commonwealths and possessions, including the State of New Jersey.

18. Biogen conducts business throughout the United States, including in the State of New Jersey, and has availed itself of the laws of the State of New Jersey.

19. Biogen agreed that Teva would distribute and sell the Product throughout the United States, including New Jersey. (Agreement at § [redacted] (defining the "[redacted]")).

20. Biogen has availed itself of the privilege of conducting activities within the State of New Jersey and the laws of the State of New Jersey because, among other reasons, it regularly conducts business within the State of New Jersey, engaged a corporation with a headquarters in the State of New Jersey (Teva) as its distributor, negotiated the Agreement with Teva executives located in the State of New Jersey, shipped its products to the State of New Jersey, and intended that the Product would be distributed within the State of New Jersey.

21. This Court has general and/or specific jurisdiction over the claims against Biogen in the present action.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) because: (i) a substantial portion of the transactions and wrongs complained of herein, including the Defendant's primary participation in the wrongful acts detailed herein

occurred in this District; (ii) Defendant regularly conducts business in this District; and (iii) Defendant has received substantial compensation arising from this District by doing business here and engaging in numerous activities that had an effect in this District, such as the payment from Teva to Biogen for the Product.

THE PARTIES

23. Plaintiff Teva Pharmaceuticals USA, Inc. is incorporated in the state of Delaware and maintains a US headquarters at 400 Interpace Parkway, Parsippany, NJ 07054. Teva specializes in the manufacture and sale of generic drugs and biopharmaceuticals.

24. Defendant Biogen International GmBH is a Swiss corporation that maintains a principal place of business in Neuhofstrasse, 30, 6340 Baar, Switzerland. Biogen International GmBH is the international affiliate of Biogen, Inc.

FACTUAL BACKGROUND

A. Tecfidera® and the Creation of the Generic Product

25. Biogen owns United States Patent 8,399,514 (the '514 Patent).

26. Biogen manufactures a pharmaceutical product containing dimethyl fumarate (the "[redacted]," (Agreement at § [redacted])), which it markets as Tecfidera®. (Agreement § [redacted]).

27. Tecfidera® is a prescription medicine approved to treat relapsing forms of MS.

28. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Mylan Pharmaceuticals, Inc. ("Mylan") filed an Abbreviated New Drug Application ("ANDA") seeking approval from the United States Food & Drug Administration (FDA) to market a generic dimethyl fumarate product for the treatment of MS, prior to the expiration of the '514 patent.

29. In response to Mylan's ANDA filing, Biogen sued Mylan for patent infringement. Mylan counterclaimed, seeking a declaratory judgment that the '514 Patent was invalid and not infringed.

30. Following a February 2020 bench trial (the "Patent Litigation"), the district court concluded that Mylan had satisfied its burden of showing that the '514 Patent claims were invalid, and issued a decision on June 22, 2020 holding as much.

31. The United States Court of Appeals for the Federal Circuit affirmed the decision of the District Court in an opinion dated November 30, 2021. *Biogen Int'l GMBH, et al. v. Mylan Pharmaceuticals Inc.*, No. 2020-1933, 18 F.4th 1333 (Fed. Cir. November 30, 2021), *cert. denied*, No. 21-1567 (Oct. 3, 2022).

32. The rulings in the Patent Litigation exposed the market for Tecfidera® to generic competition. And indeed, Mylan launched its generic product "at risk" after the District Court had issued its ruling in June 2020, and several other generic manufacturers subsequently launched generic versions of Tecfidera® as well.

33. These generic entrants deeply discounted their prices compared to Tecfidera®, significantly reducing Biogen's anticipated revenues.

34. Relatedly, the decisions in the Patent Litigation had the potential to increase the importance of other drugs manufactured by Biogen to treat multiple sclerosis that could be significantly more profitable for Biogen relative to Tecfidera® depending on the timing and extent of generic competition for Tecfidera®.

35. If a significant number of generic competitors were to obtain FDA approval and launch their competing generic products, Tecfidera® would become an essentially worthless Product for Biogen relative to other products in its portfolio (including other drugs manufactured by Biogen to treat multiple sclerosis).

B. The Agreement with Teva

36. Under the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv), a company that is the first to file an ANDA for a generic drug that is ultimately approved by the FDA is entitled to a 180-day exclusivity period, during which time the FDA cannot approve other generic products equivalent to the same brand drug. During this same 180-day period, however, brand manufacturers are permitted to launch authorized generics, and often do so in an effort to recoup some of the monopoly profits that are lost by generic market entry.

37. Upon information and belief, Biogen entered into the Agreement with Teva in an effort to join in the impending generic competition to Tecfidera®, and salvage as much revenue as possible, but when it became apparent that competition from other generic players would be more significant than initially anticipated, it decided to cut its losses and exit the market – and force Teva to do the same.

38. On or about August 25, 2020, the Effective Date, the Parties entered into an Agreement wherein Biogen engaged Teva to "[redacted]" manufactured by Biogen within [redacted]. Agreement at §§ [redacted].

39. The "[redacted]" for distribution of the Product is defined as "t[redacted]" Agreement at § [redacted].

40. The Agreement defines "[redacted]" as:

[redacted]

[redacted]

Agreement at § [redacted]. The Product is thus an authorized generic version of Tecfidera®.

41. The Distribution Period is defined as "[redacted]." *Id.* at § [redacted]. The Launch Date refers to "[redacted]." *Id.* at § [redacted].

42. The Term of the Agreement commenced on the Effective Date – August 25, 2020 – and would "[redacted]." *Id.* at § [redacted].

43. On or about September 15, 2020, Biogen provided a Launch Notice to Teva designating September 15, 2020 as the Launch Date.

44. Section [redacted] of the Agreement provides that, "[redacted]

[redacted].” *Id.* at § [redacted].

45. The Agreement further provides that Teva “[redacted].” *Id.* at § [redacted].

46. Under Section [redacted] of the Agreement, [redacted]. *Id.* at § [redacted].

47. As of March 21, 2021, Teva had purchased and was in possession of more than $[redacted] worth of Generic Product inventory under the terms of the Agreement. *Id.* at [redacted].

1. The Suspension Notice

48. It appears that, upon realizing the full scope of competition from other generic versions of Tecfidera®, and in light of the possibility that Product sold by Teva might take sales from other medicines in its portfolio also approved for treatment of MS, Biogen decided to cut bait on the Product, and set in motion a scheme both (a) to prevent Teva from selling it and (b) to prevent Teva from being

made whole as a result of Teva's inability to sell it – first by suspending Teva's rights to sell the Product, and then by terminating the Agreement altogether, while also trying to extend the suspension of Teva's rights in perpetuity.

49. Whatever its motivation, Biogen implemented a scheme that enriched itself by accepting payment for Product from Teva and then trying to prevent Teva from exercising its rights under, or obtaining any benefit from, the Agreement.

50. Under the terms of the Agreement, Biogen had the right to unilaterally suspend Teva's right to distribute the Generic Product:

[redacted]

Id. at § [redacted].

51. The Agreement defines a Suspension Period as "[redacted]

[redacted]

[redacted]." *Id.* at § [redacted].

52. [redacted]

53. Section [redacted] of the Agreement outlines [redacted]

54. Section [redacted] of the Agreement sets forth [redacted]. *Id.* at § [redacted].

55. Under Section [redacted], these [redacted]." *Id.* at § [redacted].

56. Teva incurred no Failure to Supply Penalties due to the Suspension Period.

57. Meanwhile, Section [redacted] of the Agreement [redacted]:

[redacted]

Id. at § .

58.

59. Put differently,

60. On or about March 10, 2021, Biogen notified Teva that "

." A copy of the March 10, 2021 letter from Biogen to Teva ("Suspension Notice") is attached as Exhibit B.

61. Section of the Agreement sets forth

.

62. Section [redacted] does not expressly address [redacted].

63. As of March 12, 2021 – two days after the March 10, 2021 Suspension Notice – Teva was in possession of the following inventory:

NDN Number	Material	Batch	Expiration Date	Total
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
[redacted]	[redacted]			[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
[redacted]	[redacted]			[redacted]
				[redacted]

64. Biogen never replaced or caused to be replaced any Short-Dated Generic Product in Teva's possession pursuant to Section [redacted] of the Agreement and any such replacement Product would now be valueless in light of the Termination.

2. The Termination Notice

65. On or about April 2, 2021, l[redacted]:

[redacted]

A copy of the April 2, 2021 letter from Biogen to Teva ("Termination Notice") is attached as Exhibit C.

66. Section [redacted] of the Agreement provides, "[redacted]." Agreement at § [redacted].

67. Section [redacted] governs [redacted]. *Id.* at § [redacted].

68. In particular, under Section [redacted], for any termination by Biogen under Section [redacted], Teva [redacted]:

[redacted]

[redacted]

Id. at § [redacted] (emphasis added).

69. Despite the express authorization granted to Teva under Section [redacted]

70. The Agreement provides no support for Biogen's position that [redacted]

71. In the event of termination under Section [redacted], as noted above, Teva "[redacted]." *Id.* at § [redacted].

72. Biogen's termination thus automatically triggered [redacted]

73. By nonetheless purporting to continue the Suspension Period beyond the date of termination, [redacted] in direct breach of Section [redacted] of the Agreement.

74. By terminating the Agreement, Biogen sought to avoid replacing Short-Dated Product, leaving Teva without a remedy under Section [redacted]

75. And by insisting that the Suspension remain in effect, notwithstanding its termination, Biogen sought to prohibit Teva from selling off Product that had not become Short-Dated.

76. In short, Biogen used the Termination provision to avoid its obligations under the Suspension provisions of Section [redacted] and used the Suspension provision to [redacted]

77. Biogen seeks only the benefits of the Suspension and Termination provisions without the attendant obligations, depriving Teva of the rights and benefits for which it bargained.

78. Biogen took Teva's money and left Teva with worthless Product.

79. The value of the Generic Product inventory already paid for by Teva equals $[redacted].

80. The shelf life of the Product has expired or will soon expire and, as a result, it cannot be sold. The Product is commercially worthless, as a result of Biogen's tactics.

81. To date, despite repeated requests, Biogen has refused to compensate Teva for the now worthless inventory Teva purchased and for which Biogen has been paid, but which Biogen nonetheless forbade Teva from selling following Biogen's termination.

82. To date, Biogen has refused to compensate Teva for the cost of the damages it incurred as a result of Biogen's improper denial of the benefits of the Agreement by foreclosing Teva from selling off its inventory in violation of the Agreement, and is therefore liable for breach of contract.

83. As a result of Biogen's failure to observe Sections [redacted] and [redacted] of the Agreement, Teva has suffered and will continue to suffer substantial harm and sufficient damages as a result, which include, but are not limited to, the costs of the Generic Product inventory already paid for by Teva, totaling at least $[redacted].

CAUSES OF ACTION

COUNT ONE: BREACH OF CONTRACT

84. Plaintiff incorporates by reference each and every allegation contained in the above paragraphs.

85. Teva has, at all times, performed all stipulations, conditions, and obligations stated in the Agreement and has done so in the manner specified therein, while Biogen has failed and refused to satisfy its obligations under the Agreement.

86. Biogen breached the Agreement by [redacted]

87. The clear intent and effect of Biogen's Notice of Termination was t[redacted] and signal to Teva that, if it did exercise its rights under the Agreement, Biogen would not pay Teva for sales of the Product and/or would bring action against Teva for not complying with the terms of the Notice.

88. Biogen's actions in connection with the Notice breached Section [redacted].

89. Biogen's actions also breached Section [redacted] by leaving Teva without reimbursement for Product that Biogen caused to expire.

90. Biogen's breach is material and goes to the essence of the Agreement.

91. As a direct and proximate result of Biogen's breach, Teva has been, and will continue to be, harmed.

WHEREFORE, Plaintiff Teva seeks judgment against Defendant Biogen in an amount not less than $[redacted] in compensatory damages, plus pre-judgment/post-judgment interest, statutory damages plus interest, attorney's fees, costs, and such other and further relief as the Court deems appropriate and just.

COUNT TWO: BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

92. Plaintiff incorporates by reference each and every allegation contained in the above paragraphs.

93. In the alternative, i.e. even if Biogen did not breach the express terms of the Agreement, Biogen's position that the Suspension Period remains in effect beyond the date of Termination – and, thus, in perpetuity – violates the duty of good faith and fair dealing by enriching Biogen and foreclosing Teva from receiving any benefits of the Agreement.

94. Biogen deprived Teva of the benefits for which it bargained.

95. The Agreement is a binding and enforceable contract between Teva and Biogen.

96. The Agreement between Teva and Biogen contained an implied covenant requiring Biogen to fully, honestly and reasonably perform the terms and conditions of the Agreement.

97. The Agreement is silent as to the precise circumstances here, where Biogen maintains that a Suspension Notice may remain in full force and effect, in

perpetuity, post-Termination, to foreclose both (a) Teva's right to "[redacted]" under Section [redacted] and (b) Teva's right to [redacted] under Section [redacted].

98. Section [redacted] does not reference Suspension Periods or Suspension Notices.

99. The very essence of the Agreement provides [redacted]

100. Biogen's attempt to unilaterally impose a Suspension Period that remains in effect post-termination – and, thus, in perpetuity – is a bad faith interpretation of the Agreement and was intended to prevent Teva from exercising its rights under the Agreement while enriching Biogen.

101. Biogen breached the covenant of good faith and fair dealing implicit in the Agreement by purposefully and knowingly denying Teva the benefits of the Agreement under Section [redacted] even while it retained Teva's payment.

102. Biogen breached the covenant of good faith and fair dealing implicit in the Agreement by denying Teva the benefits of the Agreement by [redacted]

103. Despite requests, Biogen has also failed to reimburse Teva for the $[redacted] inventory it paid for and received prior to the Suspension Notice and

subsequent Termination, but was unable to sell due to the Suspension Notice and subsequent Termination, including the Product that has Short-Dated.

104. The effect of Biogen's bad faith is to leave Teva with Product inventory that it has paid for and cannot sell.

105. Biogen has thereby deprived Teva of any benefits of the Agreement.

106. As a direct and proximate result of Biogen's willful, knowing and intentional breach of its covenant of good faith and fair dealing, Teva has sustained and will continue to sustain substantial loss of earnings and benefits.

WHEREFORE, Plaintiff Teva seeks judgment against Defendant Biogen in an amount not less than $[redacted] in compensatory damages, plus pre-judgment/post-judgment interest, statutory damages plus interest, attorney's fees, costs, and such other and further relief as the Court deems appropriate and just.

COUNT THREE: UNJUST ENRICHMENT

107. Plaintiff incorporates by reference each and every allegation contained in the above paragraphs.

108. At all times relevant herein, Teva conferred benefits upon Biogen in the form of payments for the Generic Product pursuant to the Agreement.

109. At all times relevant herein, Biogen had knowledge of the benefits conferred by Plaintiffs.

110. Biogen voluntarily accepted, retained, and appreciated the benefit of the payments provided by Teva.

111. Teva enriched Biogen by the benefits provided.

112. [redacted], as Section [redacted] of the Agreement expressly allows, Biogen denied Teva the benefits and protections of the Agreement.

113. Teva asserts that the value of the Generic Product inventory already paid for by Teva equals at least $[redacted].

114. Despite the receipt of the enrichment, Biogen has refused to make full payment to Plaintiffs for enrichment received.

115. Biogen's enrichment is unjust.

116. Biogen's retention of benefits under these circumstances violates fundamental principles of justice, equity, and good conscience; the circumstances render Biogen's retention of benefits inequitable unless Biogen pays Teva for the value of the benefits received.

117. As a result of Biogen's unjust enrichment, Teva is owed $[redacted], plus any additional pre-judgment and post-judgment interest and costs.

WHEREFORE, Plaintiff Teva seeks judgment against Defendant Biogen in an amount not less than $[redacted] in compensatory damages, plus pre-

judgment/post-judgment interest, statutory damages plus interest, attorney's fees, costs, and such other and further relief as the Court deems appropriate and just.

Respectfully submitted,

Dated: May 5, 2023

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